IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Confirmation No.
Ruben *et al.*	Art Unit: 1647
Appl. No. 09/345,373	Examiner: Saoud, C.
Filed: July 1, 1999	Atty. Docket: 1488.036000A
For: **Keratinocyte Growth Factor-2**	

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Reply To Restriction Requirement

Commissioner for Patents
Washington, D.C. 20231

Sir:

The Examiner has required election of "species" (*i.e.*, sequence) within the previously elected group.

In order to be fully responsive, Applicants hereby provisionally elect, with traverse, the subject matter of a polypeptide comprising amino acids 69-208 of SEQ ID NO:2, as designated by the Examiner. Applicants reserve the right to file one or more divisional applications directed to non-elected subject matter should this requirement be made final. In such case, Applicants retain the right to petition from this requirement of species election under 37 C.F.R. § 1.144.

Applicants respectfully traverse and request the withdrawal of the requirement for election of "species."

As a threshold matter, Applicants point out that MPEP § 803 lists the criteria for a proper restriction requirement:

> Under the statute an application may properly be required to be restricted to one of two or more claimed inventions only if they are able to support separate patents and they are either independent (MPEP § 806.04 – § 806.04(i)) or distinct (MPEP § 806.05 – § 806.05(i)).

> If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions.

Thus, even assuming, *arguendo*, that the groups listed by the Examiner represented distinct or independent inventions, restriction remains improper unless it can be shown that the search and examination of both groups would entail a "serious burden." *See* M.P.E.P. § 803. In the present situation, no such showing has been made.

Although the Examiner has asserted that, for example, polypeptides comprising amino acids 69 to 208 of SEQ ID NO:2 and polypeptides comprising amino acids 63 to 208 of SEQ ID NO:2 are distinct, Applicants submit that a search of the amino acids 63 to 208 of SEQ ID NO:2 would also provide useful information for amino acids 69 to 208 of SEQ ID NO:2. Indeed, since all the sequences of the claims are directed to portions of the same sequence (SEQ ID NO:2), a search of each of them would largely, if not entirely, overlap. Thus, the search and examination of all of the sequences of the claims would not entail a serious burden.

Applicants respectfully point out that the Examiner has not disclosed <u>any</u> statutory or regulatory basis for requiring the election of an individual sequence within the previously elected Group I. Applicants note that the Examiner is requiring an election of the members of the Markush-type claims (claim 43), Applicants respectfully point out that MPEP § 803.02 requires that "[i]f the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all claims on the merits." Applicants submit that the members of the Markush groups of the pending claims are sufficiently few in number <u>and</u> very closely related, as they are all different *portions of the same amino acid*

sequence, so that a search of all of the members may be made without a serious burden, contrary to the Examiner's position. Moreover, even assuming that examination of the entire claim would present a serious burden, MPEP § 803.02 states that "[f]ollowing election, the Markush-type claim will be examined fully as to the elected species and further to the extent necessary to determine patentability." If no prior art is found "that anticipates or renders obvious the elected "species," the search of the Markush-type claim will be extended." *Id.* (emphasis added).

Moreover, Applicants respectfully remind the Examiner that upon allowance of a generic claim, Applicants will be entitled to the consideration of additional "species" which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. MPEP § 809.02(a).

Further, Applicants point out that the Examiner has not addressed MPEP § 803.04, directed to nucleotide sequences. Pursuant to the notice *Examination of Patent Applications Containing Nucleotide Sequences*, 1192 O.G. 68 (November 19, 1996), §803.04 holds that even when nucleotide sequences encoding different proteins are contained in an application, a reasonable number, normally ten sequences, will be examined in a single application. Applicants submit that the instant amino acid sequences constitute different fragments of the same protein, rather than different proteins as contemplated by § 803.04. "[N]ucleotide sequences encoding the same protein are not considered to be independent and distinct inventions and will continue to be examined together." Thus, Applicants respectfully submit that the present requirement for election is improper. However, even if the Examiner contends that the instant polypeptides are different proteins within the scope of §803.04, Applicants submit that a reasonable number of such polypeptides should be examined

together, and the Examiner has given no indication why ten sequences are unreasonable in the present case.

Thus, Applicants respectfully request that the requirement for election of species be withdrawn so the restricted subject matter can be examined together.

Applicants point out that at least the following claims are readable on the provisionally elected species: claims 127-134.

Reconsideration and withdrawal of the Restriction Requirement, and consideration and allowance of all pending claims, are respectfully requested.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor are hereby authorized to be charged to our Deposit Account No. 19-0036.

Respectfully submitted,

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